

Application No. 10/607,077
Response dated April 30, 2007
Response to Office Action dated October 31, 2006

REMARKS

The Claim Amendments

Applicant has amended claim 45 to clarify that the claimed method uses the plurality of species-specific probes as PCR probes to assay the genomic DNA to determine if it contains the marker DNA that correlates with the parameter of interest. Applicant has made a similar amendment to claim 46 in the context of a hybridization-based assay.

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Claim Interpretation

The Examiner continues to argue that the term “PCR-based assay,” as used in step c of former claim 45, can be broadly interpreted to include a PCR step anywhere in the claimed assay. While applicant believes this construction is mistaken, it has amended claim 45 (and the claims that depend from it) to clarify how and when PCR is used in the claimed assay.

As amended, claim 45 recites that the species-specific probes are used as PCR probes of the genomic DNA to determine whether or not the nucleic acid marker sequence is present in the genomic DNA. This clarifying amendment makes plain where the recited PCR step occurs in the assay. *See* page 27, lines 25-28.

The Examiner also continues to assert that the correlation (“perfect,” “high” and “moderate”) is not defined. The Examiner is mistaken. Page 29, lines 4-17, defines the terms using a standard statistical analysis:

Perfect	$r = 1$
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High	$r = 0.8 - 0.99$
Moderate	$r = 0.5 - 0.7$

Rejections

35 U.S.C. §102(b) - Anticipation

Claims 45-50 stand rejected under 35 U.S.C. §102(b) as being allegedly anticipated by Telang et al., *Can. J. Microbiol.*, 40:955-964 (1994) (“*Telang*”). According to the Examiner, *Telang* refers to a method of identifying environmental parameters of interest by providing an environmental sample containing a microbial population of interest, isolating genomic DNA from the sample, performing an assay of the genomic DNA using a plurality of “species-specific” probes to a nucleic acid marker sequence that shows a correlation to a parameter of interest, and inferring the presence of the parameter of interest in samples based on the presence of the marker DNA. More particularly, the Examiner asserts that *Telang* teaches a perfect, a high degree or a moderate degree of correlation between hybridization to the probes and the presence of the parameter of interest. Applicant traverses.

Applicant’s claimed invention and *Telang*’s method are totally different. Applicant’s claimed invention is based on creating profiles of microbial diversity from samples and analyzing the profiles to correlate the presence of specific nucleic acid markers with desired parameters in a sample. *See*, page 1, Technical Field of the Invention. The methods of the claimed invention, thus, comprise identifying and using specific DNA sequences as molecular indicators or markers, wherein the presence or abundance of these indicators or markers specifically correlates with a parameter of interest. More particularly, claims 45 and 46, and the

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claims that depend therefrom, are directed to methods of identifying environmental parameters of interest using probes that correlate to the desired parameter.

By contrast, *Telang* does not teach or suggest the use of the claimed assay. Rather, *Telang* merely characterizes the diversity of sulfate-reducing bacteria in various soil or waste water environmental samples. Nothing in *Telang* correlates the presence of any specific sulfate-reducing bacteria, much less the whole collection of them, in a given sample with any parameter of interest.¹ Indeed, *Telang*'s only conclusion from all of its assays is that sulfate-reducing bacteria in soil and waste water "constitute a genetically diverse group of microorganisms" (p. 963, left hand column, last paragraph).

Notwithstanding these recitations in *Telang*, the Examiner contends that *Telang* teaches a method of identifying an environmental parameter of interest. Apparently, the Examiner holds the view that the presence of sulfate-reducing bacteria is "a parameter of interest." That view is mistaken. As *Telang* makes clear, the presence of sulfate-reducing bacteria is not a marker of any parameter of interest. Indeed, the bacteria occurs in soil and water samples from diverse sites. See, e.g., Abstract, second last paragraph. This is true whether the "correlation" is perfect, high or moderate. In sum, *Telang*'s method, and more importantly the information produced by it, are totally different from applicant's method and the information produced by it.

¹ One of *Telang*'s probes is specific for one species of sulfate-reducing bacteria – desulfovibrio. However, *Telang* does not suggest or teach that this bacterial species correlates to any environmental parameter of interest. Indeed, it is present in many of the diverse and unrelated samples tested. See Figure 3.

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In addition, *Telang* used PCR *only* to generate its 16S rDNA probe. *See* p. 957, second full paragraph. *Telang* does not use PCR when assaying whether or not the probe sequence is present in the genomic DNA of the sample. Rather, *Telang*, uses dot blots or Southern blots in that assay. *See* pp. 957-960.

Finally, contrary to the Examiner's assertions, *Telang* does not teach or suggest that the presence of sulfate-reducing bacteria correlates with oil and gas fields. Indeed, *Telang* shows just the opposite. The bacteria is present in diverse soil and water samples -- some from mines affected by acid mine damage, some from samples used to study pipeline corrosion, some from sediments of tailing ponds at tar sand extraction plants and some from oil fields. In no case did *Telang* identify a specific marker sequence that distinguished those samples or that correlated with the presence of "a subsurface oil or natural gas deposit," as required in claim 50. For that reason alone, claim 50 is patentable over *Telang*.

Accordingly, applicant requests that the rejection be withdrawn.

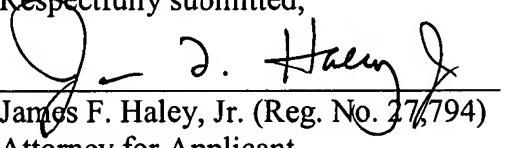
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CONCLUSION

Applicant requests consideration of the amended claims in view of the foregoing remarks and allowance of those claims.

Should the Examiner feel that a telephone conference with applicant's representative would assist the Examiner, she is invited to telephone the undersigned at any time.

Respectfully submitted,


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